I. Remarks

Claims 1-3, 5, 8, 11, 14-18 and 46-48 are pending in this application. New Claim 49 is added herein.

Claims 4, 6-7, 9-10, 12-13, 23-24, 26-27 and 32-33 were cancelled in Applicant's Response dated 12/26/2006 and Claims 19-22, 25, 28-31, and 34-45 are cancelled herein. The cancellation of these claims should not be construed as an abandonment of the subject matter covered by the cancelled claims. It is Applicant's intent to file a divisional application directed to this subject matter.

Minor amendments have been made to Claims 1-3, 5, 8, 11, 14-18, and 46-48 which are procedural in nature and which do not introduce new matter into said claims.

New Claim 49 is fully supported by the specification and particularly at paragraph **[0019].**

Note that Applicant uses the title, "Gas OR LIQUID FLOW SENSOR" in this Response. The title of the Application was changed from "SENSOR FOR DETECTING AIR FLOW" to this title by amendment made in the Response dated 09/05/2006. Applicant assumes that this amendment was entered. If this is not the case, it would be appreciated if the Examiner would so indicate.

Accompanying this Response is a Petition for Extension of Time (PTO/SB/22) for a 3-month extension of time as well as the required fee.

II. Rejection Under 35 U.S.C §102(b)

Examiner has finally rejected the pending claims under 35 USC §102(b) as follows:
Claims 1-3, 5, 8, 11, 14-18, and 46-48 are rejected under Section 102(b) as being anticipated by Stasz (US Pat. 5,311,875) and Claims 35-45 are rejected as being anticipated by Ritson (US Pat. 5,522,378).

A. Rejection of Claims Over Stasz Reference

1. Rejection of Claim 1

Claims 1, 19, and 34 are rejected as anticipated by Stasz on the grounds that Stasz discloses a sensor comprising a flexible substrate (12), a flexible transducer (10), first and second electrical contacts (22 and 24), protective covering (14 and 16), and at least one flexible lead (32). Claims 19 and 34 have been cancelled leaving the rejection applicable only to Claim 1.

Examiner is correct that both Stasz and Applicant describe a sensor having a flexible substrate. However, the substrate of Applicant is just that, a substrate that supports the other elements of Applicant's sensor. On the other hand, the flexible substrate of Stasz is a flexible polyvinylidene fluoride (PVDF) film substrate exhibiting piezoelectric and pyroelectric properties. A portion of the piezoelectric film substrate has a thin, flexible, semi-transparent layer of metallization

adhered to each surface of the PVDF film. It is these elements in combination that form the transducer described by Stasz.

The flexible PVDF film of Stasz possesses dynamic characteristics. That is to say, it develops an electrical charge proportional to changes in mechanical stress or strain imposed on it. It also acts as a pyroelectric dynamic device developing an electrical charge proportional to temperature changes to which the film is exposed. The flexible film used in Applicant's sensor does not exhibit piezoelectric and/or pyroelectric properties. Accordingly, there is a significant difference between the sensor of Stasz and the sensor of Applicant.

There are significant differences between the transducer disclosed by Stasz and the one claimed by Applicant. First of all, the sensor of Stasz and the transducer element of the sensor are attached directly to the patient. And as the patient breathes in and out, the expired and inspired breaths are directed onto the sensor and it reacts directly to (i) the pressure of a breath, especially to an expired breath and (ii) to the temperature of said breath. The sensor claimed by applicant is a bend or flex sensor. The whole sensor bends when a gas such as air or a liquid impinges on the sensor causing it to bend and causing the resistive ink transducer element of the sensor to crack producing an electric signal related to the amount of angular displacement of the sensor.

The Stasz reference specifically teaches that resistive ink sensors are different from piezo- and pyro-electric sensors. At Col 1, lines 40-62, the reference teaches that the EdenTec Corporation, manufactures and sells an air flow sensor designed to be adhesively attached to a patient's upper lip so as to be exposed to the tidal flow of respiratory gases during inspiration and expiration. The sensor sold by EdenTec contains a transducer comprised of a substrate on which is deposited a resistive ink which is a thermistor, i.e., a material exhibiting a significant resistance change with changes in temperature. A drawback of the prior art sensor is that resistive printed inks have a small temperature coefficient producing a very small change in resistance of about 0.05% with the typical 1° to 2° C. temperature change that occurs when breathing onto the sensor. As a result, the signal voltage output is very small. The invention of Stasz overcomes this drawback by using a piezo material that has pyroelectric properties producing output voltages that are approximately 1,000 times greater than the resistive printed ink sensor. These larger signals make it easier to detect small changes of temperature.

There is no "flexible lead" structure shown in the sensor of Stasz that is comparable to the one shown **in Fig 1A** and **Fig. 1B** of Applicant. Referring to **Fig. 1** of Stasz, the metallized portion of the sensor of Stasz which is the transducer, has a tail portion **32** and **34** which fold on to each other so the tail may be inserted directly into an electrical connection **42** of **Fig. 3**. In contrast, the flexible lead **16** of Applicant, is an area of the sensor **10** which is composed of the same film material as area **12** of sensor **10**. At least one flexible lead **16** hingedly connects inlet-covering portion **14** to mounting portion **18** of sensor 10. The flexible leads **16** are adapted to allow inlet-covering portion **14** of the sensor to flex easily when impinged upon by flowing gas or liquid.

2. Rejection of Claims 2 & 3

Claim 2 and Claim 3 are rejected over Stasz on the ground that the reference discloses a protective covering that substantially covers the flexible transducer and the first and second contacts.

Both Stasz and Applicant describe and claim a sensor that has a protective film covering the sensor. Referring to **Fig. 2** of Stasz, a non-porous film layer **30** covers the transducer portion of the Stasz sensor and an adhesive layer **28** covers the back portion, i.e., the part stuck to the patient. (Col. 3, lines 43-49). The film layer **12** of Stasz is the piezo-and –pyro-electric film PVDF. The PVDF film with the layer of metallization as shown in **Fig. 2** of Stasz is the transducer portion of the sensor. The sensor of Stasz does not have a first and second contact as those structures exist in Applicant's sensor.

Referring to **FIG. 1** of Stasz, the transducer component of the sensor includes an elongated tail segment **32** having the conductive strips **34** and **36** on opposed major surfaces of the tail. A slit **38** is made through the end of the piezoelectric/pyroelectric film **12** to facilitate folding of the terminal portion **40.** When so folded, the metallization on opposed sides of the strip will be aligned with one another but separated by a layer of insulation such that the folded end segments of the tail can be inserted into an electrical connector **42** to mate with wires **44** and **46** which lead to the electronic circuitry. (See **Fig 3.**)

The transducer of Stasz connects (mates) directly to wires which lead to the electronic circuitry which processes the data received form the sensor. In contrast, one end **24**a of transducer **22** of Applicant, is electrically coupled to an electrical contact **26**a and an electrical conductor **28** extends between the second end **24**b of the transducer and a second electrical contact **26**b to electrically couple the second end of the transducer to the second electrical contact **26**b. Unless the portion of the sensor **14** which covers an inlet is flexed, no electrical signal is sent to the controller. Theoretically, when the sensor of Stasz is attached to a patient, unless the patient is dead, the transducer continuously sends electrical signals to the electrical circuits described in Fig. 4 and fig. 5 of Stasz. The circuit functions one way when the patient breathes normally and another way when the patient stops breathing or has intermittent breathing.

3. Rejection of Claim 5

Examiner is correct that Stasz describes a prior art sensor which uses a resistive ink as part of the transducer. Stasz differentiates between the sensor of his invention that does not use a resistive ink and the prior art. Thus, one skilled in this art are taught that sensors having transducer using resistive ink are different from sensors having transducers having a metallized piezoelectric film.

The resistive ink sensor described by Stasz at Col. 1, lines 40-62, utilizes a resistive ink which is a thermistor, i.e., a material which exhibits a significant resistance change with changes to temperature. In contrast, the resistive ink transducer used in the sensor of Applicant is a flex or bend sensor and as the sensor bends, the resistive ink cracks producing a resistance change.

4. Rejection of Claim 8

Examiner rejects claim 8 of Applicant's claimed invention contending the following:

> Stasz discloses the flexible substrate to have a first and second side, the first and second contacts being affixed to the first side of the substrate, the third contact is affixed to the second side of the substrate and is in communication with the first electrical contact and the fourth contact is affixed to the second side of the flexible substrate and is in communication with the second electrical contact; wherein the first and third

> contacts are in communication and the second and fourth contacts are in communication.

Referring to **Fig. 2** of Stasz, the flexible substrate **12**, i.e., the PVDF film, has a layer of metallization **18** & **20** on each side. The substrate and the layers of metallization together form the transducer element of the sensor of Stasz. There is no "first and second contact" fixed to the first side of the substrate much less a third and fourth contact. No such structures are disclosed by Stasz. Referring to **Fig. 1** and **Fig. 3** of Stasz, structures **22** and **24** are lobes of the sensor that are inserted into the nares of a patient. In the sensor claimed by Applicant, no such structures exist.

5. Rejection of Claim 11 & Claim 14

Claim 11 is rejected on the grounds that Stasz discloses an "inlet" portion and that **Fig. 3** discloses this inlet portion. A consideration of **Fig. 3** clearly reveals that there is not an inlet portion shown in **Fig. 3**. Examiner further contends that Stasz discloses contacts (**22** and **24** of **Fig. 1**) that are affixed to a mounting portion (**28**). Elements **22** and **24** of Stasz are not electrical contacts but lobes that are inserted into the nostrils (nares) of the patient. What Examiner refers to as a "mounting" portion is actually a pressure sensitive adhesive that adheres the sensor to the skin of the patient. See Col. 3, lines 42-48.

6. Rejection of Claim 14

Claim 14 is rejected over Stasz, on the grounds that the reference discloses contacts that are affixed to a mounting portion. As argued above, nothing in Stasz describes electrical contacts that are equivalent to those (see **Fig. 1B** structures **26a** and **26b**) in the sensor of Applicant. The structure that Examiner calls a "mounting portion" is actually a pressure sensitive adhesive for sticking (affixing) the Stasz sensor in the nares and on the skin of the patient. Unlike the sensor of Stasz, the sensor disclosed by Applicant is not stuck to the skin of a patient nor does it have to be in contact with a patient to be useful.

7. Rejection of Claims 15-16

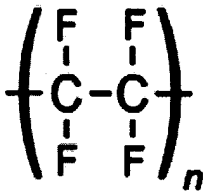
Examiner rejects Claims 15-16 on the grounds that Stasz discloses that the electrical value of the transducer changes in proportion to the flexure of the substrate and that the value increases as the substrate is flexed. In the context of the Stasz invention, this statement is incorrect. The flexible film used by Stasz is a piezoelectric and pyroelectric film which has been metallized. It is the film plus metallized portion of the sensor that acts as the transducer. The film detects both the temperature of a breath as well as the pressure an expired or inspired breath exerts as it flows over the sensor. Nothing has to bend for this to happen. Stasz clearly explains this at Col. 3, lines 34-41 where it is taught that:

> The zones of sensitivity of the transducer are those that include overlapping metallization on the opposed major surfaces. Thus, while the entire KYNAR film serves as a substrate, only those portions effectively sandwiched between the metallized electrodes contribute to the voltage developed due to temperature shifts or applied force changes. [emphasis added]

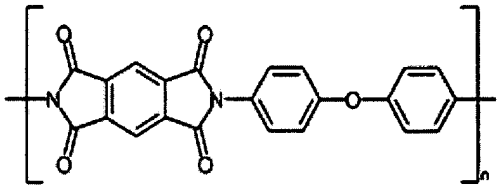
8. Rejection of Claim 17

Claim 17 is rejected on the grounds that Stasz discloses a flexible substrate made of polyimide. This is not a fair reading of Stasz. The reference teaches that PVDF may be used in the sensors of Stasz.

Polyvinylidene fluoride polymers and polyimide polymers are chemically distinct and have quite different properties. PVDF has the chemical formula



while polyimide, e.g., has the formula



Those skilled in the art would not equate the PVDF film used by Stasz with the polyimide films used by Applicant in the sensors of his invention.

9. Rejection of Claim 18

Examiner rejects claim 18 on the grounds that the sensor of Stasz is placed in the nares of the patient and thus are positioned in a stream of moving air. Examiner is correct that Stasz discloses that the sensor of Stasz is adhered to the nares of a patient and that the patient breathes in and out over the sensor. However, Claim 18 is directed to a sensor according to. according to claim 1 wherein the sensor forms at least a portion of a one-way valve in a stream of moving gas. There is nothing in Stasz that indicates that the sensor of Stasz forms a one-way valve.

10. Rejection of Claims 46 & 47

Claims 48 and 47 are rejected over Stasz on the grounds that Stasz discloses a transducer affixed to a lead. As noted above, Stasz teaches that the zones of sensitivity of the transducer are those that include overlapping metallization on the opposed major surfaces. Thus, while the entire PVDF film serves as a substrate, only those portions effectively sandwiched between the metallized electrodes contribute to the voltage developed due to temperature shifts or applied force changes. Structure **32** which Examiner regards as a "lead" is actually the tail portion of the transducer portion of the sensor. Examiner's reading of the reference is in error and thus, the rejection of Claims 46-47 can not stand.

B. Rejection of Claims 35-45 Over Ritson

Since Claims 35 to 45 are no longer pending in the Application it is contended that the rejection of Claims 35-45 has been obviated and should be withdrawn.

C. Analysis

In order to "anticipate" an invention a prior reference must disclose to one of ordinary skill in the art all elements and limitations of the patent claim. See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (1991). If the prior art reference lacks an element of a claim at issue it can not anticipate. See *Al-Site Corp v. Opti-Ray Inc.* 28 USPQ2nd 1915, 1920 (E.D. N.Y. (1993).

The Stasz reference cannot anticipate any of Applicant's claims because the sensor described by Stasz is a piezoelectric/pyroelectric sensor while the sensor claimed by Applicant is a flex or bend sensor. A bend sensor is not the same as a piezoelectric/pyroelectric sensor. A bend sensor works not by the detection of pressure or temperature, but by providing a signal related to the amount of angular displacement of a body to which it is attached.

When the transducer element of the Stasz sensor (**Fig. 2**) is compared to the transducer portion of Applicant's sensor (**Fig. 1B**), it is clear that the transducers are quite different. The Stasz transducer has a film covering over a layer of metallization, a flexible piezoelectric/pyroelectric film (PVDF), another layer of metallization, and finally a layer of adhesive material. In contrast, the transducer of Applicant (**Fig. 1B**), is a rectangular strip of flexible film e.g., KAPTON® coated with a resistive ink.

As discussed above, none of the significant features found in Applicant's claimed invention and the invention disclosed by Stasz, are the same as illustrated by, but not limited to the following list:

1. There is no "flexible lead" structure shown in the sensor of Stasz that is comparable to the one shown **in Fig 1A** and **Fig. 1B** of Applicant;

2. The sensor of Stasz does not have a first and second contact as those structures exist in Applicant's sensor;

3. One skilled in this art are taught that sensors having transducers using resistive ink are different from sensors having transducers made from metallized piezoelectric film;

4. The sensor disclosed by Applicant is not stuck to the skin of a patient nor does it have to be in contact with a patient to be useful, unlike the sensor of Stasz;

5. Stasz teaches that while the entire KYNAR film serves as a substrate, only those portions effectively sandwiched between the metallized electrodes contribute to the voltage developed due to temperature shifts or applied force changes;

6. Polyvinylidene fluoride polymers (KYNAR) and polyimide polymers (e.g. KAPTON) are chemically distinct and have different chemical properties; and

7. The sensor of Applicant forms at least a portion of a one-way valve in a stream of moving gas; the sensor of Stasz does not form a one-way valve.

The invention disclosed by Stasz does not disclose to one of ordinary skill in this art all of the elements and limitations of Applicants claimed invention; accordingly, the Stasz reference does "anticipate" Applicant's claimed invention within the meaning of 35 USC §102(b).

III. Conclusion

Based on the amendments and arguments made herein, it is respectfully asserted that Examiner's rejections have been overcome and that this application is in condition for allowance. Examiner is respectfully requested to withdraw all rejections and to issue a Notice of Allowance. If there are any questions regarding these amendments and remarks, Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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Name: Patricia A. Coburn

Date: February 27, 2008

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